UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

AMY EHLERS, individually, as daughter of Nancy June Urquhart, deceased, and as Executor of the Estate of Christopher M. Urquhart, Plaintiff, v. ABIOMED, INC., Defendant.	)	Case No. 4:24-cv-01465-SRC

Memorandum and Order

Nancy June Urquhart died after complications from her open-heart surgery. Now, her daughter, Amy Ehlers, seeks to hold Abiomed, Inc., the medical-device company that manufactured a heart pump used during the surgery, responsible. Abiomed asks the Court to enter judgment in its favor because, it contends, federal law preempts Ehlers's claims. Ehlers opposes the motion and also asks the Court for a chance to amend her complaint. As explained below, the Court finds that federal law does preempt each of her claims and grants Abiomed's motion and denies Ehlers's motion, as the proposed amended complaint fails to allege any claim that could survive federal preemption.

I. Background

A. Factual background

Ehlers's complaint alleges the following facts. In September 2022, Nancy (Where the Court uses first names, it does so for the sake of clarity, not to imply familiarity.) underwent an open-heart surgery to replace her mitral valve. Doc. 5 at ¶ 9. During the surgery, the surgeons

used a pump called the "Impella LDA Abiomed 5.5." *Id.* at ¶¶ 12, 14; *see also id.* at ¶¶ 10–11. Abiomed "improperly manufactured" the Impella pump used during the surgery. *Id.* at ¶ 13. Ehlers alleges that "the lead of the [I]mpella . . . was supposed to release after the surgical procedure." *Id.* But beyond this allegation, the complaint does not explain what the "lead" of the Impella was or how its failure to "release" caused any complication. *See* doc. 5. The complaint also fails to identify any other specific defect with the Impella's manufacturing. *See id.* The complaint concludes that the Impella caused Nancy to suffer from "intravascular hemolysis." *Id.* at ¶ 10. From these complications, Nancy died three days after her surgery. *Id.* at ¶¶ 9, 15.

B. Procedural background

Ehlers filed a two-and-a-half page complaint against Abiomed in Missouri state court. Doc. 5. The complaint enumerates two wrongful-death claims: (1) manufacturing defect and (2) breach of the implied warranty of merchantability. *Id.* at ¶¶ 13–18. Abiomed removed the case to this Court. Docs. 1, 11. In late November, Abiomed filed an answer and, the same day, moved for judgment on the pleadings. Docs. 18–20. In its motion, Abiomed argues that, because the United States Food and Drug Administration (FDA) approved the Impella with a premarket-approval supplement, federal law preempts Ehlers's claims, which sound in state tort law. Doc. 19.

After the parties fully briefed Abiomed's motion, Ehlers requested leave to file a sur-reply brief. Doc. 36. Ehlers didn't point to any new arguments that Abiomed made in its reply brief. *See id.*; *see also* doc. 35. She merely stated that her counsel was "in communication with experts regarding a [sur-reply]." Doc. 36 at ¶ 2. Finding additional briefing unwarranted, the Court denied Ehlers's request. Doc. 37.

A week later, Ehlers informed the Court that one of the plaintiffs, Christopher Urquhart, had died. Doc. 38. Ehlers also stated that she planned to move for leave to amend her complaint, presumptively to update the complaint to reflect Christopher's death. *Id.* at ¶ 2. Ehlers moved for leave to amend her complaint the next day. Doc. 39. Two days after that, Ehlers filed a renewed motion for leave to amend, doc. 41, with a proposed amended complaint, doc. 41-1, attached.

The proposed amended complaint does a lot more than remove Christopher from the list of plaintiffs. *See* doc. 41-1. The proposed amended complaint spans fifty pages and contains over two-hundred allegations, many of which relate exceptionally technical descriptions of the device at issue and copious lists of regulations that Ehlers argues that Abiomed violated. *See id.* The proposed amended complaint enumerates four claims: (1) negligence, (2) strict product liability, (3) breach of express warranty, and (4) breach of implied warranty. *See id.* Abiomed contests Ehlers's request for leave to amend. Doc. 44.

Two-and-a-half months later, Ehlers filed three more documents. Docs. 46–48. First, she filed a Motion for Substitution of Parties, in which she requests that the Court substitute her, as Executor of the Estate of Christopher M. Urquhart, for Christopher. Doc. 46. Second, she filed a memorandum to support that request. Doc. 47. Third, she filed a Notice of Hearing. Doc. 48. In the Notice of Hearing, Ehlers explains:

> Pursuant to Federal Rule[] of Civil Procedure 25(a)(3), Plaintiffs are required to file a Notice of Hearing. However, pursuant to Local Rule 4.02, Motions are submitted on memorandum [sic] without oral argument. Plaintiffs neither request oral argument nor a formal hearing, but send this Notice of Hearing for technical compliance with Federal Rule[] of Civil Procedure 25(a)(3) only.

Doc. 48 at 1 (The Court cites to page numbers as assigned by CM/ECF.). Now, Abiomed's Motion for Judgment on the Pleadings, doc. 19, Ehlers's Motion for Leave to Amend, doc. 39,

Ehlers's Renewed Motion for Leave to Amend Complaint Pursuant to Local Rule 4.07, doc. 41, and Ehlers's Motion for Substitution of Parties, doc. 46, await the Court's review.

II. Standard

A. Substitution of party upon death

Under Federal Rule of Civil Procedure 25(a)(1), the Court "may order substitution" of a party who dies but whose claim "is not extinguished." Any party, or "the decedent's successor or representative," may move for substitution. Fed. R. Civ. P. 25(a)(1). "A motion to substitute, together with a notice of hearing, must be served on the parties as provided in Rule 5 and on nonparties as provided in Rule 4." Fed. R. Civ. P. 25(a)(3). "A statement noting death must be served in the same manner." *Id.*

B. Judgment on the pleadings

Rule 12(c) provides that after the pleadings close, a party may move for judgment on the pleadings. "As a general rule, a Rule 12(c) motion for judgment on the pleadings is reviewed under the same standard as a [Rule] 12(b)(6) motion to dismiss." *Ginsburg v. InBev NV/SA*, 623 F.3d 1229, 1233 n.3 (8th Cir. 2010). To survive a motion to dismiss pursuant to Rule 12(b)(6) for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

A plaintiff need not provide specific facts in support of his allegations, *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (per curiam), but "must include sufficient factual information to provide the 'grounds' on which the claim rests, and to raise a right to relief above a speculative level," *Schaff v. Residential Funding Corp.*, 517 F.3d 544, 549 (8th Cir. 2008) (citing *Twombly*, 550 U.S. at 555 & n.3). This obligation requires a plaintiff to plead "more than labels and

conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. A complaint "must contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under *some* viable legal theory." *Id.* at 562 (citation omitted). This standard "simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of" the claim or element. *Id.* at 556.

At the motion-to-dismiss stage, the Court accepts as true all the factual allegations contained in the complaint, even if it appears that "actual proof of those facts is improbable," *id.*, and reviews the complaint to determine whether its allegations show that the pleader is entitled to relief, *id.* at 555–56; *see also* Fed. R. Civ. P. 8(a)(2). The principle that a court must accept as true all the allegations contained in a complaint does not, however, apply to legal conclusions. *Iqbal*, 556 U.S. at 678 (stating that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" (citing *Twombly*, 550 U.S. at 555)). Although legal conclusions can provide the framework for a complaint, the pleader must support them with factual allegations. *Id.* at 679. A court reviews the plausibility of the plaintiff's claim "as a whole, not the plausibility of each individual allegation." *Zoltek Corp. v. Structural Polymer Grp.*, 592 F.3d 893, 896 n.4 (8th Cir. 2010).

"When considering a motion for judgment on the pleadings (or a motion to dismiss under Fed. R. Civ. P. 12(b)(6)), the court generally must ignore materials outside the pleadings, but it may consider 'some materials that are part of the public record or do not contradict the complaint' as well as materials that are 'necessarily embraced by the pleadings.'" *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999) (first quoting *Mo. ex rel. Nixon v. Coeur D'Alene Tribe*, 164 F.3d 1102, 1107 (8th Cir. 1999); and then quoting *Piper Jaffray Cos. v. Nat'l Union Fire Ins. Co.*, 967 F. Supp. 1148, 1152 (D. Minn. 1997)); *see also Cent.*

Telecomms., Inc. v. City of Jefferson City, 589 F. Supp. 85, 91 (W.D. Mo. Feb. 29, 1984) ("The scope of a court's inquiry on a rule 12(b)(6) motion is limited to the pleadings.").

C. Leave to amend

Under Rule 15(a)(2), unless a party may amend its pleading as a matter of course, the party "may amend its pleading only with the opposing party's written consent or the court's leave," which the court "should freely give . . . when justice so requires." But "[a] district court may appropriately deny leave to amend 'where there are compelling reasons such as undue delay, bad faith, or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment.'" *Moses.com Sec., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1065 (8th Cir. 2005) (quoting *Hammer v. City of Osage Beach*, 318 F.3d 832, 844 (8th Cir. 2003)).

III. Discussion

A. Ehlers's Motion for Substitution of Parties

The wrongful-death claims arise under Missouri law. *See* doc. 5 at ¶ 5 (citing Mo. Rev. Stat. § 537.080). Abiomed doesn't *dispute* that Missouri substantive law applies to the claims, but it doesn't *agree* that Missouri law applies, either. *See* docs. 19–20, 35. A federal district court "must apply the choice-of-law rules of the forum state." *Interstate Cleaning Corp. v. Com. Underwriters Ins. Co.*, 325 F.3d 1024, 1028 (8th Cir. 2003) (first citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); and then citing *Brown v. Home Ins. Co.*, 176 F.3d 1102, 1105 (8th Cir. 1999)). Because the complaint alleges that the surgery at issue took place in Missouri, *see* doc. 5 at ¶¶ 8–9, the Court has little difficulty concluding—under Missouri choice-of-law principles—that Missouri substantive law applies to the claims. *See Elmore v. Owens-Ill., Inc.*, 673 S.W.2d 434, 437 (Mo. 1984) (applying Missouri law in a product-liability case where

the plaintiff and defendant "came in contact through the [allegedly defective] product" in Missouri).

To the extent that Christopher *had* a wrongful-death claim before he died on January 18, 2025, *see* doc. 38 at ¶ 1, his claim survives his death, *see* Mo. Rev. Stat. § 537.020.1 ("Causes of action for death shall not abate by reason of the death of any party to any such cause of action, but shall survive to the personal representative of such party bringing such cause of action and against the person, receiver or corporation liable for such death and his or its legal representatives."). Upon review of Ehlers's Motion for Substitution of Parties and the accompanying exhibits, *see* docs. 46, 46-1, 46-2, the Court finds substitution appropriate. As Ehlers "waives any further notice and formal hearing on" the motion, doc. 47 at 1, the Court grants the motion without further proceedings, *see Columbian Bank & Tr. Co. v. Miller*, 384 F. App'x 524, 524–25 (8th Cir. 2010) (per curiam) (affirming the grant of a motion to substitute where the district court granted the motion "without an evidentiary hearing"). Thus, pursuant to Rule 25(a), the Court orders the substitution of Amy Ehlers, as the Executor of the Estate of Christopher M. Urquhart, for Christopher M. Urquhart as a plaintiff in this case.

B. Abiomed's Motion for Judgment on the Pleadings

Abiomed argues that federal law preempts Ehlers's claims, which all sound in Missouri tort law. Docs. 19–20. The Court agrees with Abiomed.

1. Background on premarket approval and federal preemption

The federal Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.), an amendment to the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–399i, sorts medical devices into three classes: Class I, Class II, and Class III, *see* 21

U.S.C. § 360c(a). The parties agree that the Impella is a Class III medical device. *See* doc. 20 at 2; doc. 34 at 5. In general, a device becomes a Class III device only if "insufficient information exists to determine that" the controls imposed on Class I and Class II devices would suffice "to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(C)(i). To become subject to Class III treatment, a device must also be "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or it must "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii).

Because of the risks that Class III devices present, the MDA requires new Class III devices to go through "a rigorous regime of premarket approval." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008); *see* 21 U.S.C. § 360e. Through the premarket-approval process, the FDA must, among other things, determine whether the device has "a reasonable assurance of safety and effectiveness" and make sure that the device's "proposed labeling is neither false nor misleading." 21 U.S.C. § 360e(d)(1)(A). Once a device has received premarket approval, with only a few exceptions, the manufacturer may not change the device in any way "that affects safety or effectiveness" without submitting to the FDA a supplemental application. 21 U.S.C. § 360e(d)(5)(A)(i).

The MDA contains an express preemption clause. It says, with a limited exception:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel*, the Supreme Court of the United States held that section 360k(a) preempted state common-law negligence and strict-liability claims related to the safety of a Class III medical device.[1] 552 U.S. at 330. The *Riegel* plaintiff alleged that a catheter caused him severe injuries, and he asserted strict-liability, breach-of-implied-warranty, and negligence claims against the manufacturer. *Id.* at 320. First, the Court explained that premarket approval imposes MDA "requirements" on Class III medical devices. *Id.* at 322–23. Next, the Court held that the plaintiff's common-law causes of action for negligence and strict liability also imposed "requirements" and that those common-law "requirements" plainly related to the safety and effectiveness of the catheter. *Id.* at 323–24. Finally, the Court reasoned that "the duties underlying" the common-law claims imposed requirements "with respect to" the device because, even though the common law imposed *general* tort duties, the plaintiff still sought to impose those requirements on the manufacturer's catheter *specifically*. *Id.* at 327–28. Thus, the Court concluded that the preemption statute applied, and the Court accordingly affirmed the dismissal of the plaintiff's claims. *Id.* at 330.

The *Riegel* Court, however, left the door open to state tort claims that "'parallel,' rather than add to, federal requirements." *Id.* at 330 (citation omitted). The Court hypothesized that if

[1] In *Riegel*, issues of agency deference arose but did not control. *See* 552 U.S. at 326–27. First, in interpreting the word "requirement," in section 360k(a), the Court noted that "the FDA has supported the position taken by our opinion with regard to the meaning of the statute." *Id.* at 326. But the Court "found it unnecessary to rely upon that agency view" in interpreting the statute because, the Court concluded, "the statute itself speaks clearly to the point at issue." *Id.* In addition, the petitioners cited to an FDA regulation in support of their interpretation. *Id.* at 328 (quoting 21 C.F.R. § 808.1(d)(1)). But the Court concluded that that regulation "[could] add nothing to [its] analysis but confusion." *Id.* at 329. So the Court "[n]either accept[ed] nor reject[ed] the proposition that [the] regulation [could] properly be consulted to determine the statute's meaning." *Id.* at 329–30. At bottom, because the *Riegel* Court did *not* defer to the FDA's interpretation of the MDA's preemption clause, the Supreme Court's recent jurisprudence on agency deference does not call *Riegel*'s statutory interpretation into question. *Cf. Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 413 (2024) (holding that "courts need not and . . . may not defer to an agency interpretation of the law simply because a statute is ambiguous").

a state "provid[ed] a damages remedy for claims premised on a violation of FDA regulations," then the preemption clause wouldn't preempt the claims because the state duty wouldn't add anything to the federal requirements. *Id.*

But *Riegel* doesn't give individual plaintiffs a license to sue manufacturers for any and every violation of the FDCA. With a limited exception, "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a); *see* 21 U.S.C. § 301; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (noting that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical[-]device provisions").

In *Buckman*, the Supreme Court held that the FDCA impliedly preempted a plaintiff's attempt to enforce FDA regulations. *See* 531 U.S. at 353. The plaintiffs claimed that they had suffered injuries from a manufacturer's orthopedic bone screws, a Class III medical device. *Id.* at 343–44. They alleged that, when the manufacturer sought FDA approval for the bone screws, the manufacturer's consultant (the defendant) made fraudulent representations to the FDA about the screws' safety and effectiveness, in violation of the FDCA. *Id.* at 343–44, 349. The plaintiffs asserted state-law fraud claims against the consultant. *Id.* at 346–47.

The Court explained that the claims conflicted with the federal statutory scheme, which "amply empowers the FDA to punish and deter fraud against the" FDA and which reflects the FDA's efforts "to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. Among other things, the Court explained, federal law empowers the FDA to investigate suspected fraud, seek injunctive relief against fraud, and pursue criminal and civil penalties for fraud. *Id.* at 349. And potential applicants for medical-device approval would bear a heavy

burden if they had to comply with "the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes," a burden that Congress didn't intend to impose. *Id.* at 350. Finally, the Court noted that "the fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements." *Id.* at 353. Because "the existence of . . . federal enactments [was] a critical element in [the plaintiffs'] case," the private fraud-on-the-FDA cause of action "would exert an extraneous pull on the scheme established by Congress." *Id.*

So if a plaintiff must make a "parallel" claim to avoid *express* preemption, but, at the same time, a plaintiff can't privately enforce the FDCA without running afoul of *implied* preemption, then what state tort claims *can* a plaintiff assert for injuries arising out of a Class III medical device? The United States Court of Appeals for the Eighth Circuit answered this question in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010). The court explained:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In re Medtronic, 623 F.3d at 1204 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

In *In re Medtronic*, the plaintiffs sued a manufacturer for injuries from a component of an implantable cardiac defibrillator (a Class III device). *Id.* at 1203, 1207. The plaintiffs asserted state-law claims of, to name a few, failure to warn, defective design and manufacturing, breach of express warranty, and fraud. *Id.* at 1203. The district court granted the manufacturer's motion to dismiss, and the Eighth Circuit, after going through the different claims, affirmed. *Id.*

First, the Eighth Circuit held that section 360k(a) expressly preempted the plaintiffs' failure-to-warn claims. *Id.* at 1205–06. Those claims depended on whether the device "presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect." *Id.* at 1205. And the claim "did not allege that [the manufacturer] modified or failed to include FDA-approved warnings;" instead it alleged that "by reason of state law, [the manufacturer] was required to give additional warnings." *Id.* That meant that section 360k(a) applied. *Id.*

As for the plaintiffs' claims that the manufacturer "failed to provide the FDA with sufficient information and did not timely file adverse[-]event reports, as required by federal regulations," the Eighth Circuit again affirmed the district court's dismissal. *Id.* For these claims, the Eighth Circuit relied on *Buckman*. *Id.* The court described these claims as "simply an attempt by private parties to enforce the MDA," an attempt that couldn't survive *Buckman*'s interpretation of section 337(a). *Id.* at 1205–06.

The Eighth Circuit dispatched the design-defect claims under the express-preemption provision of section 360k(a). *Id.* at 1206. "Absent concrete allegations that the product sold by [the manufacturer] was not the product design approved in the [premarket approval], [the design-defect claims] [were] not parallel claims." *Id.* Thus, section 360k(a) expressly preempted them. *Id.*

The Eighth Circuit held that conflict preemption precluded the plaintiffs' breach-of-express-warranty claims. *Id.* at 1207–08. "To succeed on the express[-]warranty claim . . . , [the plaintiffs would have needed to] persuade a jury that [the device was] not safe and effective, a finding that would [have been] contrary to the FDA's approval." *Id.* at 1208.

Thus, the court concluded that the district court correctly held the express-warranty claim conflict preempted. *Id.*

The court upheld the dismissal of the manufacturing-defect claims too. *Id.* at 1206–07. The hamartia of this claim, the court explained, was the plaintiffs' failure to satisfy the pleading standard. The plaintiffs "simply failed to adequately plead that [the manufacturer] violated a federal requirement specific to the FDA's [premarket approval] of [the] Class III device." *Id.* at 1207. On appeal, the plaintiffs argued that the *Twombly* standard amounted to "an impossible pleading standard because the FDA's specific federal manufacturing requirements" for the defibrillator were "accessible, without discovery, only to Medtronic and to the FDA." *Id.* at 1206. The court acknowledged that this argument "would have considerable force in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the [premarket approval] prior to commencing the lawsuit." *Id.* But the court noted that, at the district court, the plaintiffs "specifically disclaimed the need for discovery in opposing Medtronic's motion to dismiss." *Id.* at 1207. Thus, while the Eighth Circuit affirmed the dismissal of the manufacturing-defect claims, the Eighth Circuit advised lower courts to exercise "care . . . in applying *Riegel*'s parallel[-]claim principle at the pleading stage, particularly to manufacturing[-]defect claims." *Id.*

Heeding the Eighth Circuit's advice, district courts within the Eighth Circuit have allowed manufacturing-defect claims to proceed to discovery where the plaintiffs alleged that medical devices were manufactured outside the premarket-approval specifications, even though the plaintiffs failed to point to the *specific* specifications that the devices failed to satisfy. *See, e.g.*, *Welz v. Bos. Sci. Corp.*, No. 4:24 CV 820 CDP, 2024 WL 4252817, at *4 (E.D. Mo. Sept. 20, 2024) ("Although Boston Scientific complains that Welz's Amended Complaint is not

specific enough as to *how* [the device] was not manufactured in compliance with the [premarket approval], . . . Welz has done more than simply allege that Boston Scientific has violated unspecified or generic federal regulations; he has set out how the [device] was manufactured outside the specifications of the [premarket approval] and alleged the ways that those defects caused his device to fail and injure him." (emphasis added)); *Sullivan v. Medtronic, Inc.*, 498 F. Supp. 3d 1106, 1113 (E.D. Mo. 2020) ("In contrast, here Sullivan has pleaded not only particularized violations of [Current Good Manufacturing Practices] as detailed by the FDA's numerous warning letters to Medtronic (which detail the factual bases for such violations), but also that the manufacture of her device was in violation of the [premarket approval] specifications, which resulted in a defective device whose manufacture was not approved by the FDA."); *Edwards ex rel. Herrman v. Thoratec LLC*, 532 F. Supp. 3d 786, 792 (D. Minn. 2021) ("Plaintiff specifically alleges a violation of a particular PMA requirement that also constitutes a violation of state manufacturing[-]defect law.").

But district courts within the Eighth Circuit *have* dismissed manufacturing-defect claims at the pleading stage where plaintiffs' complaints *completely* failed to allege that the devices at issue fell short of premarket-approval specifications. *See, e.g.*, *Brown v. Medtronic, Inc.*, No. 4:20-cv-00295-JAJ-CFB, 2021 WL 9682170, at *4 (S.D. Iowa Mar. 10, 2021) ("First, the court notes that Brown offers no citations to his Amended Complaint showing where he ostensibly pleaded that his pump was not manufactured in compliance with the FDA[-]approved design in the [premarket approval], and the court has found none."); *Harris v. Medtronic, Inc.*, 729 F. Supp. 3d 869, 883 (D. Minn. 2024) ("Harris does not reference the [premarket-approval] process anywhere in the Amended Complaint, much less a specific violation of or deviation from it."); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 988 (E.D. Mo. 2014) (dismissing a

manufacturing-defect claim where the plaintiff attempted "to impose liability on the manufacturer despite the manufacturer's compliance with the applicable FDA design and manufacturing specification[s], as approved by the FDA during the pre-market[-]approval process" (first alteration in original) (citation omitted)).

2. Ehlers's claims

Having charted the waters, the Court now assesses whether Ehlers's claims survive preemption. The Court concludes that they do not.

First, the Court notes that the Impella received premarket approval as a Class III device. *See* docs. 18-1, 18-2; *see also Stahl v. U.S. Dep't of Agric.*, 327 F.3d 697, 700 (8th Cir. 2003) (holding that "[t]he district court may take judicial notice of public records and may thus consider them on a motion to dismiss" (citation omitted)); *Ashley Cnty. v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009) (holding that courts should apply, to a motion for judgment on the pleadings, "the same standard used to address a motion to dismiss for failure to state a claim"); *Blankenship*, 6 F. Supp. 3d at 983 n.1 (E.D. Mo. 2014) (taking judicial notice of FDA premarket and supplemental approvals on a motion to dismiss); *Welz*, 2024 WL 4252817, at *2 (same); *Arthur v. Medtronic, Inc.*, No. 4:14-CV-52 (CEJ), 2014 WL 3894365, at *1 n.1 (E.D. Mo. Aug. 11, 2014) (same). Next, the Court turns to the individual claims.

a. Manufacturing-defect claim

Ehlers's complaint states that the Impella "was unreasonably dangerous as the lead of the [I]mpella, which was supposed to release after the surgical procedure was completed, was improperly manufactured." Doc. 5 at ¶ 13. The complaint alleges nothing else about how the Impella was defective or how the alleged manufacturing defect failed to satisfy the FDA's premarket-approval requirements for the Impella. *See* doc. 5.

"[H]ere, [Ehlers] simply fail[s] to adequately plead that [Abiomed] violated a federal requirement specific to the FDA's [premarket] approval of this Class III device." *In re Medtronic*, 623 F.3d at 1207. In fact, the complaint in *In re Medtronic*—the dismissal of which the Eighth Circuit affirmed—came closer to alleging a parallel claim than Ehlers's complaint does. The *In re Medtronic* complaint alleged that the device at issue in that case "failed to comply" with the FDA's Current Good Manufacturing Practices and Quality System Regulation. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) (citation omitted). In contrast, Ehlers's complaint doesn't even mention federal requirements, let alone describe how the Impella failed to satisfy those requirements. *See* doc. 5. Thus, even exercising "care . . . in applying *Riegel*'s parallel[-]claim principle at the pleading stage, particularly to manufacturing[-]defect claims," *In re Medtronic*, 623 F.3d at 1207, the Court holds that federal law preempts Ehlers's manufacturing-defect claim because the complaint completely fails to allege that the Impella fell short of any FDA premarket-approval specifications, *see Brown*, 2021 WL 9682170, at *4; *Harris*, 729 F. Supp. 3d at 883. Ehlers's failure to explain how the Impella failed to satisfy federal requirements also explains why *Hofts v. Howmedica Osteonic Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009)—a non-binding district-court case on which Ehlers heavily relies, *see* doc. 34 at 3—doesn't apply here, *see Hofts*, 597 F. Supp. 2d at 836 ("Here it is clear that Hofts bases his tort claims on allegations that Howmedica failed to meet the FDA's requirements, not on allegations that Howmedica failed to depart from or exceed those requirements.").

In her response brief, Ehlers, in a conclusory manner, lists several federal requirements that she argues the Impella failed to satisfy. *See* doc. 34 at 6–7. But the complaint does not contain such a list; nor does it contain any factual allegations that would allow the Court to infer

that the Impella failed to satisfy any federal requirement. *See* doc. 5. Ehlers's conclusory arguments amount to, at best, nothing more than an attempt to amend her complaint by brief, an attempt that the Court rejects. *See Morgan Distrib. Co., Inc. v. Unidynamic Corp.*, 868 F.2d 992, 995 (8th Cir. 1989) ("However, it is axiomatic that a complaint may not be amended by the briefs in opposition to a motion to dismiss." (citation omitted)).

b. Implied-warranty-of-merchantability claim

Ehlers also argues that Abiomed "further breeched [sic] its implied warranty of merchantability which caused [Nancy]'s death." *Id.* at ¶ 16. To recover for breach of the implied warranty of merchantability, "a plaintiff must prove that the buyer was injured by the defective nature of the goods." *Renaissance Leasing, LLC v. Vermeer Mfg. Co.*, 322 S.W.3d 112, 130 (Mo. 2010) (citing *Ragland Mills, Inc. v. Gen. Motors Corp.*, 763 S.W.2d 357, 360 (Mo. Ct. App. 1989)). In other words, to succeed on this claim, Ehlers would need to "persuade a jury that [the Impella] [was] not safe and effective, a finding that would be contrary to the FDA's approval" of the Impella. *In re Medtronic*, 623 F.3d at 1208; *see* docs. 18-1, 18-2.

Thus, Ehlers's failure to allege how the Impella failed to satisfy federal requirements proves just as fatal to the implied-warranty-of-merchantability claim as it did to the manufacturing-defect claim. *Compare Sullivan*, 498 F. Supp. 3d at 1115–16 ("Here, where Sullivan alleges that the device was not fit for its intended purpose under Missouri law *due to Medtronic failing to manufacture the [device] in accordance with federal requirements*, the alleged breach[-]of[-]warranty claim parallels the federal requirements for the device rather than imposing different or additional requirements and is therefore not preempted by the MDA." (emphasis added)), *with Harris*, 729 F. Supp. 3d at 882 ("To succeed on [an implied-warranty-of-merchantability claim], Harris would be required to show that the [devices]

were unsafe and defective or not reasonably safe for their intended use, 'which is no different than persuading a jury that the devices are not safe and effective.'" (quoting *Kinetic Co. v. Medtronic, Inc.*, No. 08-CV-6062 (PJS/AJB), 2011 WL 1485601, at *4 (D. Minn. Apr. 19, 2011))).

The Court can discern no other claims from Ehlers's complaint. Since all claims are preempted, the Court grants Abiomed's Motion for Judgment on the Pleadings. Doc. 19.

C. Ehlers's Motion for Leave to Amend

Abiomed opposes Ehlers's request for amendment on two grounds: (1) bad faith and (2) futility. *See* doc. 44 at 1. The Court agrees that amendment would be futile, so the Court need not and does not reach the bad-faith issue.

Even under the liberal amendment rules of Rule 15(a)(2), "a party is not entitled to amend a complaint without making a showing that such an amendment would be able to save an otherwise meritless claim." *Plymouth Cnty. v. Merscorp. Inc.*, 774 F.3d 1155, 1160 (8th Cir. 2014) (citing *Wisdom v. First Midwest Bank*, 167 F.3d 402, 409 (8th Cir. 1999)). "A district court thus may deny a motion to amend a complaint when such an amendment would be futile." *Id.* "When the court denies leave [to amend] on the basis of futility, it means the district court has reached the legal conclusion that the amended complaint could not withstand a motion to dismiss" under Rule 12(b)(6). *Briscoe v. Cnty. of St. Louis*, 690 F.3d 1004, 1015 (8th Cir. 2012) (alteration in original) (quoting *Hintz v. JPMorgan Chase Bank, N.A.*, 686 F.3d 505, 511 (8th Cir. 2012)).

Here, Ehlers's proposed amended complaint has a kitchen-sink approach to it. As described below, many of the exceptionally technical allegations in the complaint bear no relevance to Ehlers's claims or theories for relief—they instead look more like an attempt to

obfuscate the issues, paint Abiomed in an unsympathetic light by pointing to red herrings, and proffer as many legal theories as possible, likely in the hope that at least *one* claim would survive the pleading stage. *See, e.g.*, doc. 41-1 at 39, ¶ 153 (listing off, without description or explanation, 22 regulations that Abiomed allegedly violated).

Ordinarily, when performing a futility analysis, the Court would proceed claim-by-claim. But, Ehlers frames her claims so broadly—and in such an uncategorized manner—that the Court cannot ascertain the claims merely by reference to the labeled counts toward the bottom of the complaint. *See generally* doc. 41-1. For instance, Ehlers labels her second claim "Strict Products Liability." *Id.* at 41 (emphasis omitted). But Ehlers does not specify whether she makes this claim under a failure-to-warn, design-defect, or manufacturing-defect theory. *See id.* at 41–45, ¶¶ 162–88. The allegations under this count seem to zero in on a failure-to-warn theory, *see id.*, but, in other parts of the complaint, Ehlers hints at a manufacturing-defect claim, *see, e.g.*, *id.* at 7 ¶ 18 (alleging that the Impella "was improperly manufactured"); *id.* at 28 ¶ 100 (alleging that "manufacturing defects can occur with the device and lead to adverse consequences for Patients"). On account of this disorganization, and because it is the alleged "factual matter" that makes or breaks a complaint at the pleading stage, *Iqbal*, 556 U.S. at 678, the Court proceeds allegation-by-allegation to determine whether Ehlers's proposed amended complaint states a non-preempted claim for relief.

The first eleven paragraphs[2] describe the parties and issues related to jurisdiction and venue. Doc. 41-1 at 4–6 ¶¶ 1–11. Paragraphs 12 through 23 appear in the original complaint,

[2] The Court notes that Ehlers's proposed amended complaint attempts to fuse her original complaint and her proposed additional allegations. *See* doc. 41-1 at 1–3 (adopting, revising, and omitting allegations from Ehlers's initial complaint); *see id.* at 4–49 (adding allegations under the heading "Plaintiff's First Amended Complaint" (emphasis omitted)). The proposed amended complaint, however, includes numerous sets of consecutively numbered paragraphs using the same method of identification (i.e., paragraph 1, 2, 3, etc.). For the sake of clarity, the Court, in this futility analysis, references the set of consecutively numbered paragraphs beginning on page four

see id. at 6–7 ¶¶ 12–23, and, as explained above, these allegations fail to state a non-preempted claim, *see supra* Section III.B.2.

Paragraphs 24 through 26 describe, in general terms, medical-device manufacturers' obligations to "provide updated safety and efficacy information to the healthcare community and to consumers." Doc. 41-1 at 8, ¶ 25; *see id.* at 8, ¶¶ 24–26. These allegations amount to, at most, legal conclusions that the Court is not required to accept as true at the pleading stage. *See Iqbal*, 556 U.S. at 678.

Paragraphs 27 and 28 state that, at the time it approved the Impella for sale in the United States, the FDA "was not aware that the device could cause serious health risks, such as hemolysis" and that, after the FDA approved the device, Abiomed "became aware of serious adverse events" but did not warn "health care providers and consumers about complaints of serious injuries associated with the Impella." Doc. 41-1 at 9, ¶¶ 27–28. But Ehlers does not allege—in these allegations or anywhere else in the complaint—that Abiomed failed to warn of the risk of hemolysis, which Ehlers later describes as the cause of Nancy's death. *See id.* at 32–34, ¶¶ 122, 124. Furthermore, Ehlers fails to allege that Abiomed "modified or failed to include *FDA-approved* warnings" rather than additional warnings, which renders any failure-to-warn claim preempted. *In re Medtronic*, 623 F.3d at 1205 (emphasis added).

In paragraphs 29 and 30, Ehlers accuses Abiomed of having "persisted in conducting a nationwide misleading marketing campaign" by representing "that Impella was safer than other methods for short term support of the pumping chambers of the heart (ventricles) during high-risk catheter-based procedures called percutaneous coronary interventions . . . or when a patient is suffering from ongoing cardiogenic shock." Doc. 41-1 at 9, ¶ 29. A few problems

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of Ehlers's proposed amended complaint. For example, the "first eleven paragraphs" referenced here refer to those spanning pages four through six of that document. Doc. 41-1 at 4–6, ¶¶ 1–11.

exist with this paragraph. First, other allegations in the proposed amended complaint undermine the premise that the Impella *was not* safer than other methods in relevant respects. *See id.* at 13, ¶¶ 45–46 (citing a New England Journal of Medicine article and saying that, relative to the use of "standard care," the use of a microaxial flow pump (like the Impella) lowers a patient's risk of death). Second, to the extent that Ehlers *can* use this allegation to support a breach-of-express-warranty claim, federal law preempts the claim because a finding that the Impella was not "safe and effective" would be contrary to the FDA's premarket approval of the device. *See In re Medtronic*, 623 F.3d at 1207–08 (holding breach-of-express-warranty claim conflict preempted).

Paragraphs 31 through 44 describe, in technical detail, how devices like the Impella can cause hemolysis. Doc. 41-1 at 10–12, ¶¶ 31–44. But nowhere—in these paragraphs or anywhere else—does the proposed amended complaint allege that the Impella caused hemolysis in Nancy *because of* any defect in the device. *See* doc. 41-1. At best, these allegations complain of the inherent risks that the Impella presents. And "attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device" fly in the face of *In re Medtronic*, and federal law "expressly preempt[s]" any claims that arise from those attacks. 623 F.3d at 1206.

Paragraphs 45 through 50 fail to state a non-preempted claim for the same reason. These paragraphs relate the findings of a study from the New England Journal of Medicine, which apparently showed that the Impella presents a lower risk of death but a higher risk of certain complications. *See* doc. 41-1 at 10–12 ¶¶ 31–44. To the extent that these allegations amount to a product-liability claim, they invite the Court to re-evaluate the FDA's decision "to approve an inherently dangerous Class III device." *In re Medtronic*, 623 F.3d at 1206. These paragraphs thus cannot support a parallel claim. *See id.* at 1205–07.

Paragraphs 51 through 59 describe the premarket-approval process and reporting requirements that Abiomed incurred as part of that process. Doc. 41-1 at 14–17, ¶¶ 51–59. These paragraphs make no allegations that could give rise to any tort claim, much less a non-preempted one.

Paragraphs 60 through 66 describe warnings and recalls that the FDA has issued for Abiomed's medical devices, including the Impella. *See id.* at 17–19, ¶¶ 60–66. According to these paragraphs, the FDA issued these warnings and recalls because of reports of "heart ventricle perforations" and "heart valve damage." *Id.* at 18, ¶¶ 61, 63. But nowhere in the proposed amended complaint does Ehlers allege that Nancy suffered heart-ventricle perforations or heart-valve damage from the Impella. *See* doc. 41-1. On the contrary, Ehlers alleges that "hemolysis, which resulted in acute kidney injury and acute renal failure" caused Nancy's death, *id.* at 32–33, ¶ 122; *see id.* at 33–34, ¶ 124, and Ehlers nowhere alleges that any of the risks that motivated the recalls or warnings of the Impella contributed in any way to her cause of death, *see* doc. 41-1. Thus, even if the risks that motivated these recalls *could* substantiate a state tort claim in a case where those risks materialized, the Court need not decide that issue because the proposed amended complaint fails to allege that those risks materialized *here*.

In paragraph 67, Ehlers alleges that Abiomed "agreed to pay $31 million to resolve allegations that it violated the False Claims Act by purchasing lavish meals for physicians in order to induce them to use Abiomed's Impella line of heart pumps." *Id.* at 19, ¶ 67 (citation omitted). That allegation has nothing to do with Nancy's death.

Paragraphs 68 through 70 generally describe how federal law imposes duties on Abiomed to provide accurate and up-to-date warning labels. *Id.* at 19–21, ¶¶ 68–70. These allegations

amount to, at most, legal conclusions that the Court is not required to accept as true at the pleading stage. *See Iqbal*, 556 U.S. at 678.

In paragraph 71, Ehlers argues that Abiomed breached its federal- and state-law duties by failing to "maintain [the] labeling" of the Impella in three ways: first, by not adding "warnings about the adverse reactions alleged herein for which there was reasonable evidence of a causal association;" second, by not adding "instructions for use that would enhance the safe use of the device;" and third, by not adding "descriptions of adverse events to ensure that the labeling was not false or misleading." Doc. 41-1 at 21, ¶ 71. Ehlers fails to articulate *what* "adverse reactions" or "adverse events" the Impella's label failed to warn about. *Id.* And more importantly, even if Ehlers *had* provided enough specificity to articulate a failure-to-warn claim in this allegation, Ehlers fails to allege that Abiomed "modified or failed to include *FDA-approved* warnings" rather than additional warnings. *In re Medtronic*, 623 F.3d at 1205 (emphasis added). That failure renders Ehlers's failure-to-warn claim preempted. *See id.*

In paragraph 72, Ehlers lists several duties that federal regulations impose on Abiomed, and, in paragraph 73, Ehlers states, in a conclusory manner, that Abiomed "failed" to satisfy those duties. Doc. 41-1 at 21–22, ¶¶ 72–73. The Court does not accept as true this "legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (citation omitted). The Court also does not assume the veracity of paragraph 74, which asserts, in a conclusory manner, that Abiomed "breached its duties to take reasonable steps to prevent foreseeable and intended risks, including to Nancy Urquhart." Doc. 41-1 at 22–23, ¶ 74.

In paragraph 75, Ehlers describes federal- and state-law duties to warn. *Id.* at 23, ¶ 75. This paragraph amounts to, at most, a legal conclusion that the Court is not required to accept as true at the pleading stage. *See Iqbal*, 556 U.S. at 678.

Paragraph 76 contains a general statement that Abiomed "failed to disclose and warn of the health hazards and risks associated with Impella" and instead "marketed, advertised, and promoted Impella while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of state law, including Missouri law, and FDA regulations." Doc. 41-1 at ¶ 76. This allegation contains nothing new.

Paragraphs 77 through 79 describe duties that federal law and Missouri law impose on Abiomed. *Id.* at 23–24, ¶¶ 77–79. These allegations amount to, at most, legal conclusions that the Court is not required to accept as true at the pleading stage. *See Iqbal*, 556 U.S. at 678.

Paragraph 80 makes a conclusory statement that Abiomed "failed to timely and/or effectively warn of the serious safety risks to the FDA and public." Doc. 41-1 at 24, ¶ 80. Again, this paragraph contains nothing new.

Paragraph 81 describes the role of the FDA Office of Regulatory Affairs. *See id.* at 24, ¶ 81. Ehlers fails to explain, however, how the Office of Regulatory Affairs bears any relevance to her proposed amended claims or theories for relief. *See* doc. 41-1.

Paragraph 82 describes FDA Form 483. *Id.* at 24, ¶ 82. Ehlers likewise fails to explain how that form bears any relevance to her proposed amended claims or theories for relief. *See* doc. 41-1.

Paragraphs 83 through 85 make more conclusory statements that Abiomed failed to report unspecified defects and risks of the Impella. *See id.* at 25, ¶¶ 83–85. These paragraphs contain nothing new.

Paragraphs 86 and 87 state that Abiomed "delayed disclosure of the safety information regarding the Impella" and "received direct financial benefit" from its "tortious conduct." *Id.* at 25, ¶¶ 86–87. These allegations have no bearing on whether a product defect existed, whether a

defect caused Nancy's death, or whether federal law preempts the tort claims that Ehlers attempts to assert.

Paragraphs 88 through 95 and paragraph 98 contain nothing more than descriptions of duties that Abiomed allegedly owed and conclusory statements that Abiomed breached those duties. *See id.* at 25–28, ¶¶ 88–95, 98. For instance, paragraphs 88, 90, 92, and 95 reference "parallel" duties under state law but fail to identify any state laws, much less any Missouri laws, and still less any facts from which the Court could infer that Abiomed violated any state law. *Id.* at 25–27, ¶¶ 88, 90, 92, 95. In paragraph 93, Ehlers states that Abiomed's labelling practice rendered the Impella a "misbranded" device under the FDCA and that this misbranding "also violated parallel state laws" (once again, without identification). *Id.* at 26, ¶ 93. But Ehlers fails to identify the defects in labelling, and she also fails to explain how any defective labelling bears any relevance to Nancy's death. *See* doc. 41-1.

Paragraphs 96 and 97 state that Abiomed's "actions violated duties under state law, including Missouri law, governing its post-marketing conduct" because Nancy and her physicians "neither knew, nor had reason to know at the time of their use of Impella, of the existence of the aforementioned adverse events and defects." *Id.* at 27, ¶¶ 96–97. But, even to the extent that these statements allege a failure to warn, they fail to allege that Abiomed "modified or failed to include FDA-approved warnings," so the paragraphs fail to state a parallel claim. *In re Medtronic*, 623 F.3d at 1205.

Paragraph 99 states:

> [Abiomed] did not have a quality control department. Instead, it contracted with an outside entity to periodically audit its manufacturing sites. During that time, the FDA inspected [Abiomed]'s manufacturing facility and issued a Form 483 notice of violation reporting that: (1) design outputs identified as essential for the proper functioning of the device were not completely identified; (2) corrective and preventive action activities had not been documented, including implementation of

> corrective and preventive actions; (3) the procedures addressing verification or validation of corrective and preventive actions were not implemented; and (4) certain adverse events were not captured in the data submitted for Impella's [premarket approval].

Id. at 28, ¶ 99. Ehlers does not explain the relevance of this allegation or its connection to her proposed amended claims or theories for relief. *See* doc. 41-1. Indeed, Ehlers fails to explain how these alleged violations caused (or were even related to) Nancy's death. *See id.* Additionally, Ehlers fails to identify any relevant state law that could support a parallel claim. *See id.* at 28, ¶ 99. At most, paragraph 99 reflects an attempt to enforce FDA regulations related to facility inspection and to attack the FDA's premarket approval of the Impella. *Id.* That attempt does not fit within the "narrow gap" within which parallel claims must fit because it reflects an attempt to sue Abiomed "*because* [its] conduct violates the FDCA." *In re Medtronic*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777).

In paragraph 100, Ehlers states that "manufacturing defects can occur with the device." Doc. 41-1 at 28, ¶ 100. She then lists four alleged "manufacturing defects" that "can occur." *Id.* This allegation has several problems. First, by saying that these defects merely "*can* occur," *id.* (emphasis added), the allegation "stops short of the line between possibility and plausibility," *Iqbal*, 556 U.S. at 678 (citation omitted). Thus, solely by the qualifying language, this allegation fails to allege facts that could state a claim for relief, because the allegation fails to state that any manufacturing defect *actually occurred* here. *See id.*

Additionally, the listed alleged defects—though Ehlers labels them "manufacturing defects"—do not describe manufacturing defects. Doc. 41-1 at 28, ¶ 100. "A manufacturing defect occurs when 'something goes wrong in the manufacturing process and the product is not in its intended condition.'" *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 791 (Mo. Ct. App. 2008) (citation omitted). But Ehlers's alleged defects don't map onto that

framework. First, she says that the Impella's Instructions for Use "do not adequately address precautions to take when treating patients who have undergone transcatheter aortic valve replacement." Doc. 41-1 at 28, ¶ 100(a). This has nothing to do with whether something went wrong in the manufacturing process for the Impella. And even if it did, nowhere does Ehlers allege that Nancy even underwent transcatheter aortic valve replacement, so the Court fails to see the relevance of this allegation. *See* doc. 41-1. Second, Ehlers says that "a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement . . . resulting in destruction of the impeller blades" exists with the Impella. *Id.* at 28, ¶ 100(b). That's not a manufacturing defect, either—that allegation instead challenges "the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device" and more closely represents a design-defect claim. *In re Medtronic*, 623 F.3d at 1206. Federal law preempts claims related to that alleged defect. *See id.* And even if it didn't, again, Ehlers nowhere alleges that Nancy underwent a transcatheter aortic-valve replacement, which means these alleged defects have nothing to do with Nancy's death. *See* doc. 41-1.

Paragraph 101 describes how Abiomed actually *addressed* many of these alleged defects. *Id.* at 29, ¶ 101. If anything, this paragraph undermines Ehlers's claims.

And if the preceding paragraphs didn't, paragraphs 102 through 111 don't help Ehlers's case, either. *See id.* at 29–30, ¶¶ 102–11. In paragraphs 102 through 108, Ehlers makes strong accusations that Abiomed engaged in misleading marketing and advertising tactics. *See id.* at 29–30, ¶¶ 102–08. And in paragraphs 110 and 111, Ehlers attempts to blame Nancy's death on these tactics:

> 102. Defendant violated the Impella CPMA and §§ 502(q) and (r) of the FDCA and parallel state laws by engaging in misleading advertising of Impella.

> 103. Defendant continued to sell their product with misleading and false advertising in violation of the conditions of the Impella CPMA and state laws.
>
> 104. Defendant's advertising practices lead [sic] to litigation in Boston, Massachusetts.
>
> 105. Defendant knew or should have known Impella's marketing campaign claims included misrepresentations and omissions of material safety information.
>
> 106. Defendant marketed the product as providing safer outcomes than other devices when studies concluded that the mortality rates were the same:[3]
>
> 107. Defendant disseminated misleading information at a time when it knew or should have known there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in the possession of Defendant.
>
> 108. Despite the fact that evidence existed that the use of Impella was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose the health hazards and risks associated with Impella to the FDA, physicians, and patients. Instead, Defendant marketed, advertised, and promoted Impella while failing to warn or otherwise ensure the safety of its users in violation of parallel state law, including Missouri law, the Impella CPMA, and FDA regulations.
>
> . . .
>
> 110. Doctors and patients, including Nancy Urquhart and her implanting physicians, relied on the misrepresentative marketing strategy developed by Defendants in Missouri.
>
> 111. Doctors and patients, including Nancy Urquhart and her implanting physicians, relied on these omissions and/or misrepresentations by Defendants.

Id. at 29–30, ¶¶ 102–08, 110–11.

Tucked between paragraphs 108 and 110 is paragraph 109, the only place in the proposed amended complaint where Ehlers gives an actual *example* of the alleged misleading advertisements: "Defendant advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets stating the following about Impella[],

[3] [*But see* doc. 41-1 at 13, ¶ 46 (admitting that a New England Journal of Medicine article showed "lower risk of death" from microaxial flow pumps like the Impella); *see generally* doc. 41-1 (failing to identify any study showing that the mortality rates were the same)]

while failing to report the actual material facts: https://www.abiomed.com/en-us/products-and-services/impella/impella-55-with-smartassist." *Id.* at 30, ¶ 109. All Ehlers provides is a link to Abiomed's website—with no identification of what on the website amounted to false or misleading advertising or marketing.

The Court visited the website that Ehlers linked to paragraph 109. After all, Ehlers—by explicitly linking the website to the complaint and by failing to explain what the website said or how the website contained a misleading advertisement—invited the reader to do so. Right after clicking the link, the Court found a short description and overview of the Impella with an "Indications for Use" section that plainly contained the following:

> **Contraindications and Warnings**
> Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Cardiac or Vascular injury (including ventricular perforation). In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices. To learn more, visit: https://www.abiomed.com/important-safety-information.
>
> **Potential Adverse Events**
> Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Cardiac or Vascular injury (including ventricular perforation). In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices. To learn more, visit: https://www.abiomed.com/important-safety-information.

Impella 5.5® with SmartAssist®, Abiomed, https://www.abiomed.com/en-us/products-and-services/impella/impella-55-with-smartassist (last visited July 21, 2025).

The advertisement that Ehlers *herself* cites as the one example of a false and misleading advertisement not only shows an explicit warning of the adverse events that Nancy allegedly suffered, *see* doc. 41-1 at 32, ¶ 122 (alleging that Nancy experienced "hemolysis, which resulted in acute kidney injury and acute renal failure"), but also shows an explicit warning of many of

the other (irrelevant) adverse events that Ehlers accuses Abiomed of not warning doctors and patients about. And although the website might have changed from the time that Ehlers last visited it until the Court visited it, Ehlers failed to put a "last visited" parenthetical on her citation to the website, *see id.* at 30, ¶ 109, so the Court cannot glean any allegation of a misleading advertisement solely by reference to the link, nor can the Court glean what warnings were on the website at the time that Nancy's doctors made the decision to use the Impella in Nancy's surgery.

Paragraphs 112 through 116 contain more conclusory allegations that Abiomed failed to disclose adverse events. *See id.* at 30–31, ¶¶ 112–16. Paragraphs 117 and 118 contain nothing more than this as well. *See id.* at 31, ¶¶ 117–18.

In paragraphs 119 through 124, Ehlers describes how Nancy died of hemolysis and renal failure. *See id.* at 31–34, ¶¶ 119–24. And in paragraph 125, Ehlers says (again) that Abiomed fraudulently concealed "the true character, quality, and nature of its device." *Id.* at 34, ¶ 125.

That takes the reader to Ehlers's listed causes of action. *See id.* at 34. The Court thoroughly reviewed the remaining paragraphs in the proposed amended complaint and finds that they contain no new factual allegations that the Court has not already addressed in the preceding paragraphs. Accordingly, the Court finds that Ehlers's proposed amended complaint could not survive a renewed motion for judgment on the pleadings and that the proposed amendment is thus futile. The Court therefore denies Ehlers's motion for leave to amend. Doc. 41.

IV. Conclusion

Accordingly, the Court orders the following. The Court grants Ehlers's [46] Motion for Substitution of Parties and substitutes Amy Ehlers, as Executor of the Estate of Christopher M. Urquhart, for Christopher Urquhart as a plaintiff in this case. The Court grants Abiomed's [19]

Motion for Judgment on the Pleadings. The Court denies as moot Ehlers's [39] Motion for Leave to Amend Complaint and denies as futile Ehlers's [41] Renewed Motion for Leave to Amend Complaint Pursuant to Local Rule 4.07. The Court enters judgment in favor of Abiomed and against Ehlers and dismisses, with prejudice, Ehlers's [5] complaint. Additionally, the Court directs the Clerk of Court to change, in the case caption, the spelling of "Urqhart" to "Urquhart" for both Christopher Urquhart and Nancy June Urquhart. The Court further directs the Clerk of Court to, on the docket sheet, remove Christopher Urquhart as a plaintiff to this case and to add Amy Ehlers, as the Executor of the Estate of Christopher M. Urquhart, as a plaintiff to this case. A separate judgment accompanies this Memorandum and Order.

So ordered this 21st day of July 2025.

STEPHEN R. CLARK
CHIEF UNITED STATES DISTRICT JUDGE